

**4379 FIRST AID KIT- 4379 first aid kit
4334 FIRST AID KIT- 4334 first aid kit
Honeywell Safety Products USA, INC**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

4334, 4379 First Aid Kit (triple, Burn Jel, alcohol wipe, PVP wipe, BZK, sting relief, Foille, aypanal EX- Z019819, Z63158006)

Triple

Active ingredients

Bacitracin zinc 400 units

Neomycin sulfate (5 mg equivalent to 3.5 mg Neomycin base)

Polymyxin B sulfate 5000 units

Triple

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Triple

Uses

- first aid to help prevent infection in
- minor cuts
- scrapes
- burns

Triple

Warnings

For external use only

Allergy alert do not use if you are allergic to any of the ingredients

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- a deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- the condition persists or gets worse

- a rash or other allergic reaction develops
- you need to use longer than 1 week

Keep out of the reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Triple

Directions

- clean the affected area
- apply a small amount of the product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage

Triple

Other information

- store at 15⁰ to 25⁰ C (59⁰ to 77⁰ F)
- tamper evident sealed packets
- do not use if packet is torn or opened

Triple

Inactive ingredient

petrolatum

Alcohol

Active ingredient

Isopropyl alcohol 70%

Alcohol

Purpose

First aid antiseptic

Alcohol

Uses

- first aid to help prevent infection in minor cuts, scrapes, and burns

Alcohol

Warnings

For external use only

Flammable, keep away from fire or flame.

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

deep or puncture wounds

animal bites

serious burns

When using this product

- do not use longer than one week unless directed by a doctor

Stop use and consult a doctor

- if condition persists or gets worse

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away.

Alcohol

Directions

- clean the affected area
- apply wipe to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard wipe after single use

Alcohol

Other information

store at room temperature 15⁰ to 25⁰ C (59⁰ to 77⁰ F)

Alcohol

Inactive ingredient

water

Foille

Active ingredient

Benzocaine 5.0% (w/w)

Chloroxylenol 0.1% (w/w)

Foille

Purpose

External analgesic

Antiseptic

Foille

Uses

- For the temporary relief of pain associated with burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations.
- First aid to help prevent infection in minor cuts, scrapes and burns.

Foille

Warnings

For external use only

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens, or symptoms persist for more than 7 days or clear up and occur again within a few days.
- Do not apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Foille

Directions

- clean the affected area.
- adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult a physician.

Foille

Other information

Avoid contact with clothing

Foille may stain certain fabrics

Burn Jel

Inactive ingredients

beeswax, benzyl alcohol, calcium disodium EDTA, calcium hydroxide, ceresin, eugenol, hydrogenated vegetable oil, maleic anhydride, mono- and di-glycerides, PEG-32, purified water, sodium borate, sodium lauryl sulfate, zea mays (corn) oil.

Burn Jel

Active ingredient

Lidocaine HCl 2.0 %v

Burn Jel

Purpose

External analgesic

Burn Jel

Uses

- temporarily relieves pain due to minor burns

Burn Jel**Warnings****For external use only****Do not use**

- on large areas of the body, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Burn Jel**Directions**

- adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor
- you may report a serious reaction to this product to 800-430-5490

Burn Jel**Other information**

- store at room temperature - do not use if opened or torn

Burn Jel**Inactive ingredients**

carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, trolamine, water

Burn Jel**Questions**

1-800-430-5490

Sting Relief**Active ingredients (in each wipe)**

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

Sting Relief**Purpose**

Antiseptic

Topical pain relief

Sting Relief

Uses

- prevent infection in minor scrapes, and temporary relief of itching of insect bites

Sting Relief

Warnings

For external use only

Flammable, keep away from open fire or flame

Do not use

- over large areas of the body
- in eyes
- over raw or blistered areas

Stop use and ask a doctor

if conditions worsen or persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Sting Relief

Directions

- adults and children 2 years and older: Apply to cleaned affected area not more than 3 times daily.
- children under 2 years of age: consult a doctor.

Sting Relief

Inactive ingredients

benzalkonium chloride, menthol, and purified water

Sting Relief

Questions or Comments?

1-800-430-5490

PVP Wipe

Active ingredient

Povidone-iodine 10% (equivalent to 1% titratable iodine)

PVP

Purpose

First aid antiseptic

PVP

USes

- first aid antiseptic to help prevent infection in minor cuts, scrapes and burns

PVP

Warnings

For external use only.

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens or persists for more than 72 hours
- irritation and redness develops

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

PVP

Directions

- clean the affected area
- apply 1 to 3 times daily
- may be covered with a sterile bandage
- if bandaged, let dry first
- discard wipe after single use

PVP

Other information

- do not use on individuals who are allergic or sensitive to iodine
- store at controlled temperature 59-86°F (15-30°C)
- do not use if pouch is open or torn

PVP

Inactive ingredients

nonoxynol 9, water

PVP

Questions

800-430-5490

Aypanal EX

Active ingredient

Acetaminophen 500 mg

Aypanal EX

Purpose

Pain reliever/fever reducer

Aypanal EX

Uses

- temporarily relieves minor aches and pains due to the common cold and headache
- temporarily reduces fever

Aypanal EX

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount.
- with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away

Do Not Use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease

Ask a doctor or pharmacist before use if

- you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

If pregnant or breastfeeding,

- ask a health professional before use.

Aypanal EX

Directions

- **do not take more than directed (see overdose warning)**
- adults and children 12 years of age and over: Take 2 tablets with water every 6 hours while symptoms last.
- do not take any more than 8 tablets in 24 hours.
- children under 12: consult a doctor

Aypanal EX**Other information**

store at room temperature 15⁰-30⁰ C (59⁰-86⁰ F)
TAMPER EVIDENT- DO NOT USE IF OPEN OR TORN

Aypanal EX**Inactive ingredients**

microcrystalline cellulose, povidone, sodium starch glycolate, starch, stearic acid

Aypanal EX**Questions or Comments?**

1-800-430-5490

BZK**Active ingredient**

Benzalkonium chloride 0.13% w/v

BZK**Purpose**

First aid antiseptic

BZK**Uses**

Antiseptic cleansing of face, hands, and body without soap and water

BZK**Warnings****For external use only****Do not use**

- in the eyes or over large areas of the body
- on mucous membranes
- on irritated skin
- in case of deep puncture wounds, animal bites or serious burns, consult a doctor
- longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

- if irritation, redness or other symptoms develop

- the condition persists or gets worse

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

BZK

Directions

- tear open packet and use as a washcloth

BZK

Other information

- store at room temperature 15⁰ to 30⁰C (59⁰ - 86⁰ F)
- do not reuse towelette

BZK

Inactive ingredients

water

BZK

Questions

1-800-430-5490

4334

Z019819 KIT CONTENTS

1 TRIPLE ANTIOTIC 10 PER

1 INSTANT COLD PACK 4" X 6"

2 ADHESIVE BDG,PLSTIC,1"X3"16PER

1 BURN JEL 1/8 OZ, 6 PER

1 ALCOHOL PREP PADS 10P

1 PVP IODINE WIPES 10 PER

1 NITRILE GLOVES 2PR BBP

1 ANTIMCRBL ANTSPTC TWLETTS

1 ADHESIVE TAPE W/P 1/2"X 5 YD

1 TWEEZER PLASTICS 4"

1 FLEXICON 2"X 4.1 YD

1 FIRST AID GUIDE ASHI

1 ABD COMBINE PAD 5" X 9"

1 SCISSOR BDGE 4" RED PLS HDL

LBL STOCK 6-3/8"X4"

LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

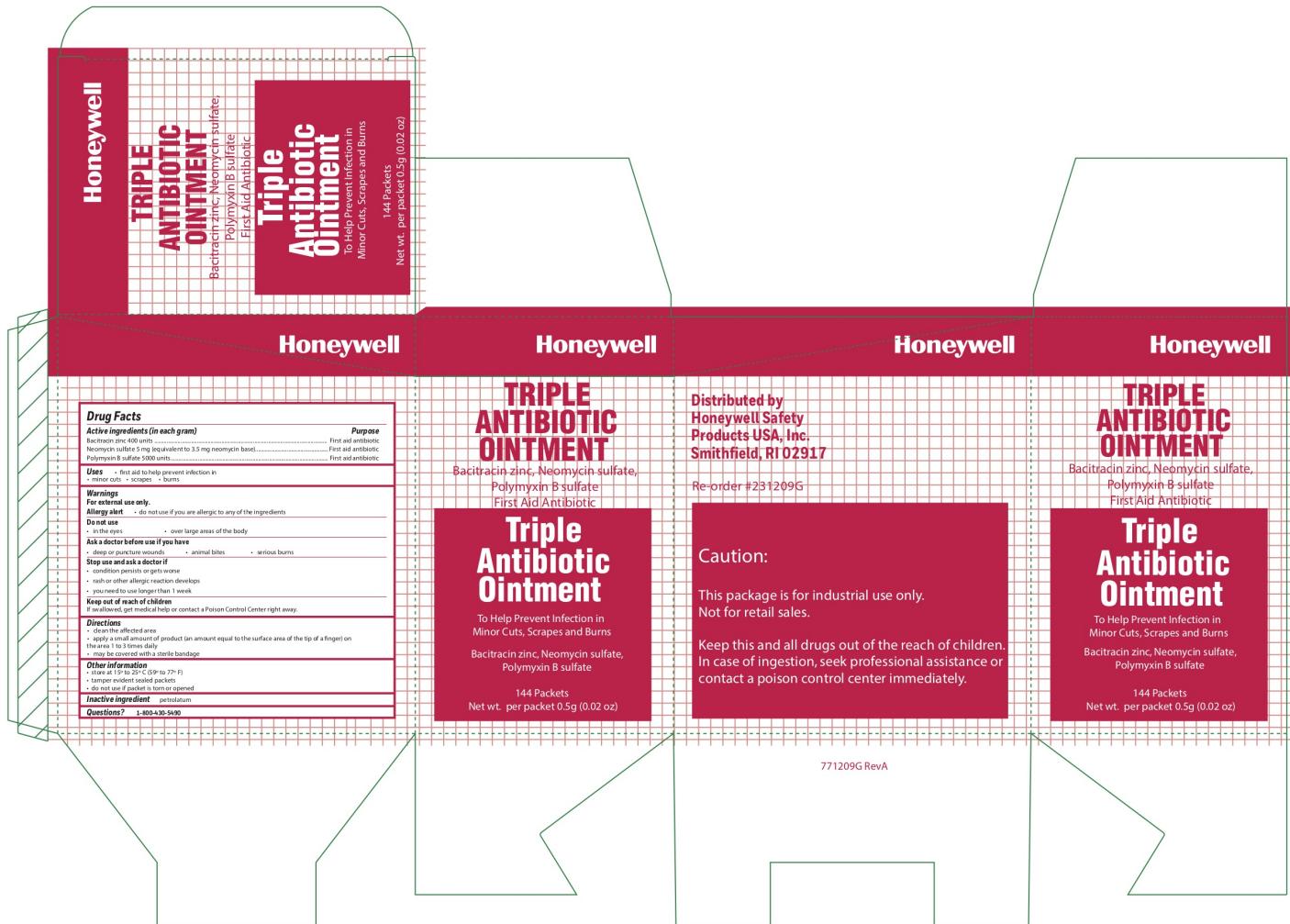
1 LBL CONTS 6 3/4"X3 1/2" ID B
1 LABEL COVER, GRAINGER Z019819
1 KIT PP 24 UNIT FA
3 SAFETEC STING RELIEF WIPES BULK
1 FOILLE BURN/F A OINT 1/2 OZ
4 GAUZE PADS 2"X2" 12PLY
1 GAUZE PADS 4"X4" 12PLY
4 WOVEN FINGERTIP BANDAGE 2"
4 WOVEN KNUCKLE BANDAGE
4 HEAVY FLEX LARGE PATCH 2" X 3"
1 GAUZE PADS 3"X3" 4/BX
1 TRIANG 37X37X52 UNIT
8 AYPANAL EXTRA BULK 2/PK

4379
Z63158002 Kit Contents

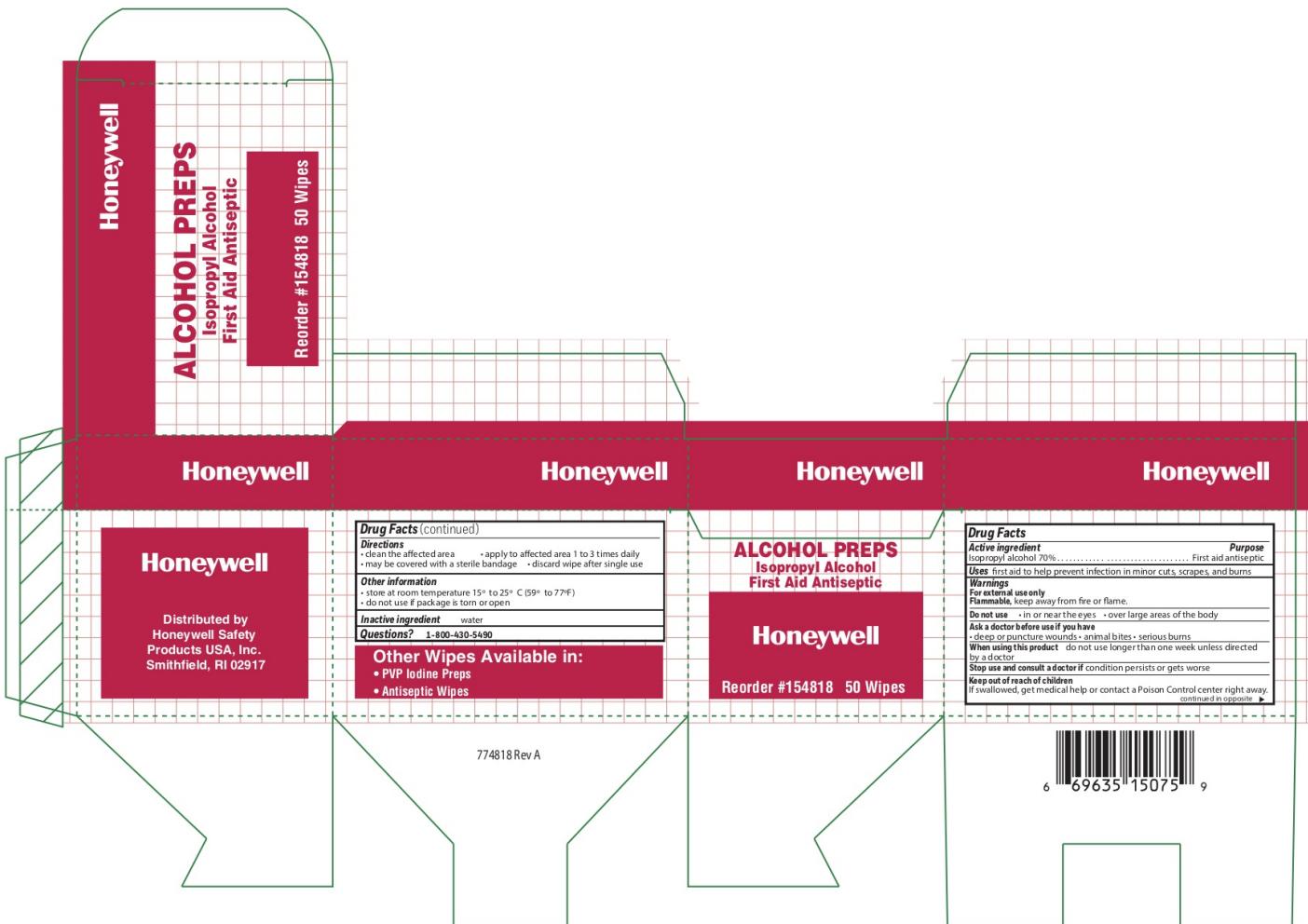
1 TRIPLE ANTIBIOTIC 10 PER
1 INSTANT COLD PACK 4" X 6"
2 ADHESIVE BDG,PLSTIC,1"X3"16PER
1 BURN JEL 1/8 OZ, 6 PER
1 ALCOHOL PREP PADS 10P
1 PVP IODINE WIPES 10 PER
1 NITRILE GLOVES 2PR BBP
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 4 GAUZE PADS 2"X2" 12PLY
 1 GAUZE PADS 4"X4" 12PLY
 4 WOVEN FINGERTIP BANDAGE 2"
 4 WOVEN KNUCKLE BANDAGE
 4 HEAVY FLEX LARGE PATCH 2" X 3"
 1 GAUZE PADS 3"X3" 4/BX
 1 TRIANG 37X37X52 UNIT
 8 AYPANAL EXTRA BULK 2/PK

Triple Principal Display Panel

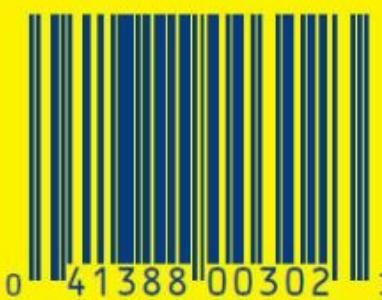


Alcohol Principal Display Panel



Foille
Principal Display Panel

Drug Facts	Active ingredients	Purpose
	Benzocaine 5.0% (w/w) Chloromycetin 0.1% (w/w)	External Analgesic Antiseptic
Uses		<ul style="list-style-type: none"> For the temporary relief of pain associated with burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations. First aid to help prevent infection in minor cuts, scrapes and burns.
Warnings		<p>For external use only.</p> <p>When using this product</p> <ul style="list-style-type: none"> Avoid contact with the eyes. Stop use and ask a doctor if condition worsens, or symptoms persist for more than 7 days or clear up and occur again within a few days. Do not apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.
		<p>Keep out of reach of children.</p> <p>If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> Clean the affected area. Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a physician.



0 41388 00302 3



MEDICATED FIRST AID OINTMENT

Fast, Soothing Relief Of Pain Due To:
Cuts & Scrapes • Minor Burns
 Sunburn • Insect Bites

NDC 10157-9302-4



MEDICATED FIRST AID OINTMENT

Fast, Soothing Relief Of Pain Due To:
Cuts & Scrapes • Minor Burns
 Sunburn • Insect Bites

NET WT.
1 oz (28g)

Drug Facts (continued)

Other information

- Avoid contact with clothing. Foille may stain certain fabrics.

Inactive ingredients

beeswax, benzyl alcohol,
calcium disodium EDTA,
calcium hydroxide, camellia,
eugenol (hydrogenated
vegetable oil), maleic anhydride,
mono- and di-glycerides,
PFB-32,
purified water, sodium
borate, sodium lauryl sulfate,
zea mays (corn) oil

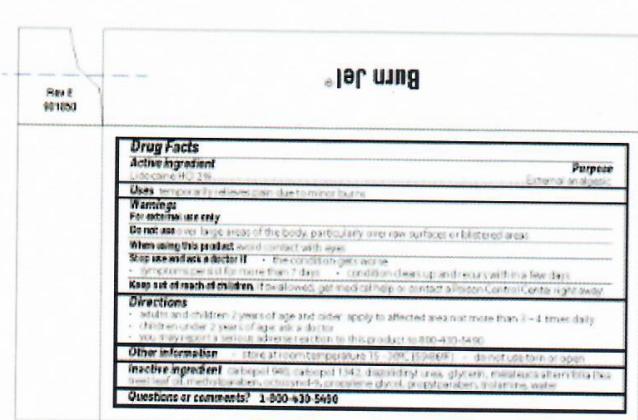
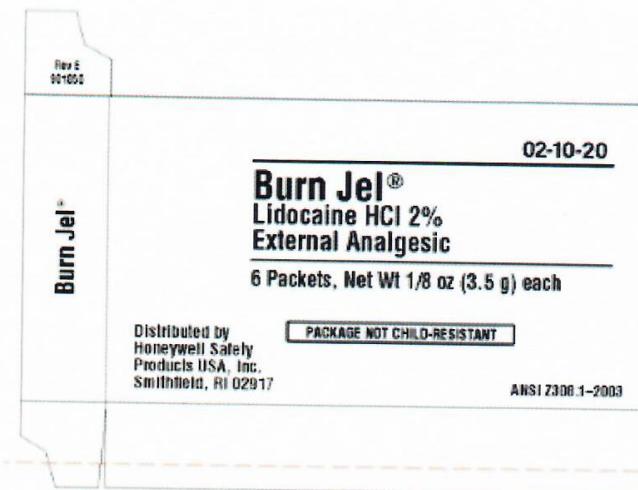


For the temporary relief of pain due to scrapes, cuts, minor burns, sunburn, non-poisonous insect bites, and minor skin irritation. Foille First Aid Ointment stops pain on contact and lets you resume normal activities right away. Foille has a medicated oil-based formula that helps heal and prevent infection.

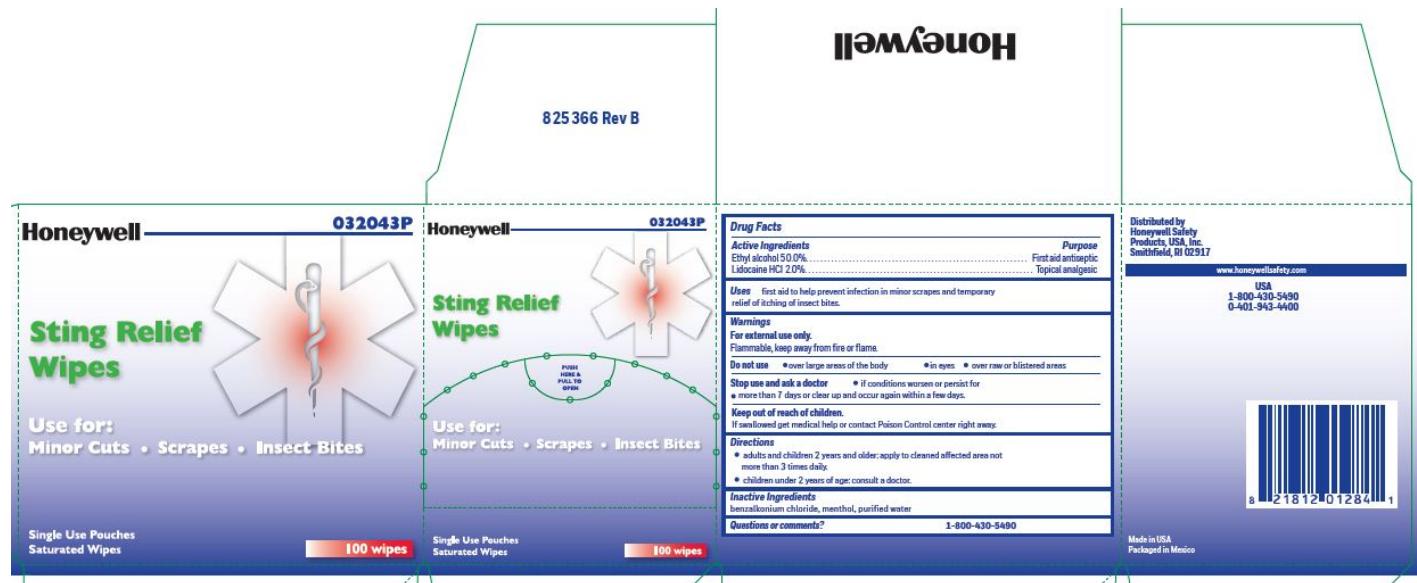
SATISFACTION
GUARANTEED
Blistex

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P.O. Box 5392
Oak Brook, IL 60522-5392
#39013
④ Carton is 100% Recyclable.

Burn Jel
Principal Display Panel



Principal Display Panel



PVP Principal Display Panel

FRUNI JUVE

822568 X
Rev. *

PVP Iodine Wipes

02-12-01X



PVP Iodine Wipes

Povidone-Iodine 10%
First Aid Antiseptic
10 Saturated Wipes
ANSI Z308.1-2009

Distributed by:
Honeywell Safety
Products USA, Inc.
Smithfield, RI 02917

822569 X
Rev. *



PVP Iodine Wipes

Drug Facts

Active ingredient

Povidone-Iodine 10% (equivalent to 1% titrable iodine) Purpose

First aid antiseptic

Use

first aid to help prevent the risk of infection in minor cuts, scrapes, and burns

Warnings

For external use only

Do not use

- in or near the eyes - over large areas of the body - on individuals who are allergic or sensitive to iodine

Ask a doctor before use if you have

- deep or puncture wounds - animal bites - serious burns

When using this product

do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if

- condition persists or gets worse - irritation or redness develops

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- clean the affected area - apply wipe to affected area 1 to 3 times daily

- may be covered with a sterile bandage - discard wipe after single use

Other information

- store at room temperature: 15-30° C (59-86° F)

- do not use if package is torn or open - do not use on individuals who are allergic or sensitive to iodine

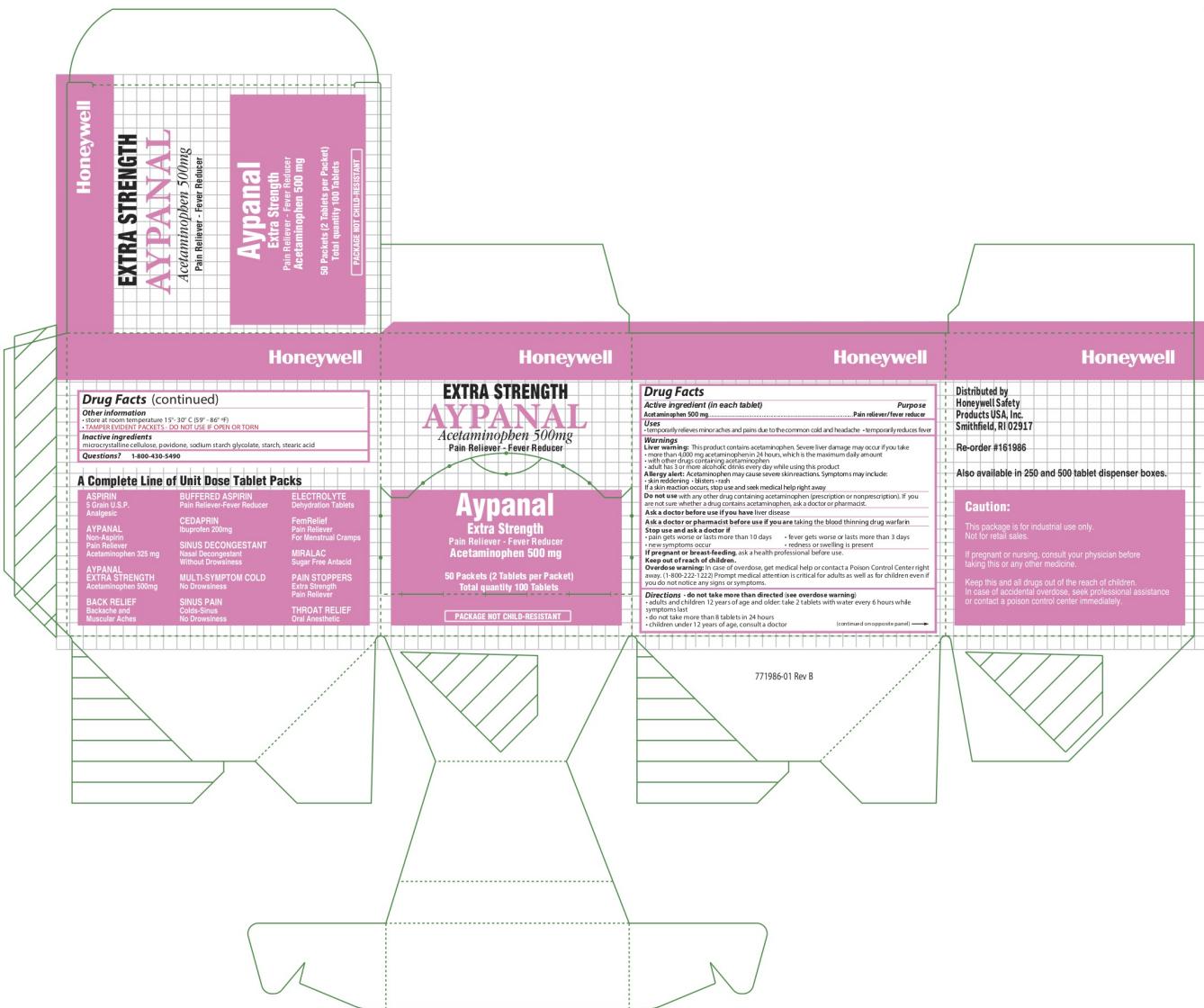
Inactive ingredients

nonoxynol-9, water

Questions or comments?

1-800-430-5490

Aypanal EX
Principal Display Panel



BZK
Principal Display Panel

47001083
Rev B

Antiseptic Towelettes

Honeywell

02-16-35MD

Antiseptic Towelettes

Benzalkonium chloride
First aid antiseptic

Six-Saturated Towelettes

Distributed by
Honeywell Safety
Products USA, Inc.
Smithfield, RI 02917

47001083
Rev B

Antiseptic Towelettes

Honeywell

Drug Facts

Active Ingredient

Benzalkonium chloride 0.133% w/v **Purpose**
First aid antiseptic

Uses

• antiseptic cleaning of face, hands and body without soap and water. • air dries in seconds

Warnings

For external use only

When using this product • do not use in the eyes or apply over large areas of the body

Ask a doctor before use • in case of deep or puncture wounds, animal bites, or serious burns

Stop use and consult a doctor if

• irritation, redness or other symptoms develop • condition persists or gets worse

Do not use • longer than 1 week unless directed by doctor

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • tear open packet, unfold and use as washcloth

Other Information

• store at room temperature 15° -30° C (59° -86° F) • do not reuse towelette

Inactive ingredient

water

Questions or comments 1-800-430-5490

**4334 Kit Label
Z019819**

FIRST AID

GENERAL PURPOSE, UNITIZED
24 PERSON



GRAINGER.COM[®]

GRAINGER[®]

||||| FOR THE ONES WHO GET IT DONE

47001728A

Distributed by Honeywell Safety Products USA, Inc. Smithfield, RI 02917

4373 Kit Label
Z63158002

46001363 Rev.C
Prints 3 colors
Black, Red (PMS 186) and Blue (PMS 072)

Refill Information

US Poison Control 1-800-222-1222



Contact your authorized Honeywell Safety Products Distributor with your refill orders.

Honeywell

www.honeywellsafety.com

USA 1-401-943-4400 1-800-430-4110	CANADA 1-514-351-7233 1-888-212-7233	EUROPE +31 (0) 118 656400
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46001363 Rev. C

4379 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4379
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4379-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 POUCH	4 mL
Part 2	1 TUBE	14 g
Part 3	6 PACKET	21 g
Part 4	1 PACKET	1.4 mL
Part 5	3 POUCH	1.2 mL
Part 6	10 POUCH	3 mL
Part 7	8 PACKET	16
Part 8	10 PACKET	9 g

Part 1 of 8

ALCOHOL WIPE

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2018	

Part 2 of 8

BLISTEX FOILLE MEDICATED FIRST AID

benzocaine and chloroxylenol ointment

Product Information

Item Code (Source)	NDC:10157-9302
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.1 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CERESIN (UNII: Q1LS2UJO3A)	
EUGENOL (UNII: 3T8H1794QW)	
MALEIC ANHYDRIDE (UNII: V5877ZJJ25)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CORN OIL (UNII: 8470G57WFM)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/05/2013	

Part 3 of 8

BURN JEL

gel for burns gel

Product Information

Item Code (Source)	NDC:0498-0203
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBO MER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBO MER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETA DISODIUM (UNII: 7FLD91C86K)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-00	3.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/19/2018	

Part 4 of 8

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source)	NDC:0498-0501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0501-00	1.4 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/21/2017	

Part 5 of 8

STING RELIEF PAD

ethyl alcohol, lidocaine swab

Product Information

Item Code (Source)	NDC:0498-0733
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/23/2017	

Part 6 of 8

PVP IODINE WIPE

povidone-iodine 10% swab

Product Information

Item Code (Source)	NDC:0498-0121
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 7 of 8

AYPANAL EX

acetaminophen tablet

Product Information

Item Code (Source)	NDC:0498-2110
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-2110-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/02/2017	

Part 8 of 8

TRIPLE ANTIBIOTIC

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

Product Information

Item Code (Source)	NDC:0498-0750
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0750-35	0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	09/19/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

4334 FIRST AID KIT

4334 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4334
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4334-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	1.4 mL
Part 2	3 POUCH	1.2 mL
Part 3	10 POUCH	3 mL
Part 4	8 PACKET	16
Part 5	10 PACKET	9 g
Part 6	10 POUCH	4 mL
Part 7	1 TUBE	14 g
Part 8	6 PACKET	21 g

Part 1 of 8

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source)	NDC:0498-0501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name		Strength
WATER (UNII: 059QF0KO0R)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0501-00	1.4 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/21/2017	

Part 2 of 8

STING RELIEF PAD

ethyl alcohol, lidocaine swab

Product Information

Item Code (Source)	NDC:0498-0733
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PL200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL

Inactive Ingredients

Ingredient Name		Strength
MENTHOL (UNII: L7T10EIP3A)		
WATER (UNII: 059QF0KO0R)		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/23/2017	

Part 3 of 8

PVP IODINE WIPE

povidone-iodine 10% swab

Product Information

Item Code (Source)	NDC:0498-0121
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 4 of 8

AYPANAL EX

acetaminophen tablet

Product Information

Item Code (Source)	NDC:0498-2110
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MICRO CRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-2110-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/02/2017	

Part 5 of 8**TRIPLE ANTIBIOTIC**

bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment

Product Information

Item Code (Source)	NDC:0498-0750
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
NEO MYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0750-35	0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	09/19/2018	

Part 6 of 8

ALCOHOL WIPE

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2018	

Part 7 of 8

BLISTEX FOILLE MEDICATED FIRST AID

benzocaine and chloroxylenol ointment

Product Information

Item Code (Source)	NDC:10157-9302	
Route of Administration	TOPICAL	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.1 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETALE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CERESIN (UNII: Q1LS2UJO3A)	
EUGENOL (UNII: 3T8H1794QW)	
MALEIC ANHYDRIDE (UNII: V5877ZJJ25)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CORN OIL (UNII: 8470G57WFM)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/05/2013	

Part 8 of 8

BURN JEL

gel for burns gel

Product Information

Item Code (Source)	NDC:0498-0203
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCaine HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETA DISODIUM (UNII: 7FLD91C86K)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-00	3.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/19/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

Labeler - Honeywell Safety Products USA, INC (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
Blistex Inc.		005126354	manufacture(10157-9302)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4334, 0498-4379)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	manufacture(0498-2110)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0750, 0498-0203)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143, 0498-0501)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Medical Biotech		532775194	manufacture(0498-0121)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America Inc		874965262	manufacture(0498-0733)

Revised: 9/2019

Honeywell Safety Products USA, INC